



October 16, 2020

Chair Senfronia Thompson and Members
House Committee on Public Health
Transmitted via email: PublicHealth@house.texas.gov

Re: House Committee on Public Health, Interim Charge 1: Monitor the agencies and programs under the Committee's jurisdiction and oversee the implementation of relevant legislation passed by the 86th Legislature. Conduct active oversight of all associated rulemaking and other governmental actions taken to ensure intended legislative outcome of all legislation, including the following: HB 2174, which establishes limits on prescribing opioids for acute pain and institutes certain requirements for controlled substance prescription submissions and continuing education for prescribers.

Dear Chair Thompson and Members:

On behalf of the Texas Federation of Drug Stores (TFDS) we appreciate the opportunity to provide written comments to the House Committee on Public Health on provisions in HB 2174 that mandate Electronic Prescribing of Controlled Substances. TFDS is an association of ten (10) chain pharmacies which operate over 3,000 pharmacies in Texas and employ over 10,000 pharmacists. TFDS represents approximately 65% of all retail pharmacies in Texas.

EPCS. HB 2174, passed in the 86th Legislative Session, 2019, contains provisions that mandate controlled substances to be electronically prescribed and provides exemptions and waivers to the mandate. The applicable Sections of the bill are 4, 5, 6, 7, 8 and 11. The provisions mandating Electronic Prescribing of Controlled Substances (EPCS) go into **effect January 2021**.

Rulemaking. Section 7 of HB 2174 added a new Sec. 481.0756, Occupations Code, which permits the appropriate regulatory agency that issued the license, certification, or registration to a prescriber to grant a prescriber a waiver from the use of EPCS. The law requires the Texas State Board of Pharmacy (TSBP) to convene a workgroup of the regulatory agencies that regulate prescribers to establish recommendations and standards for circumstances in which to grant a waiver from electronically prescribing and to develop a process. Additionally, the bill mandated that the TSBP adopt rules establishing the eligibility for a waiver for:

Economic hardship;
Technological limitations not reasonably within the control of the prescriber; or
Other exceptional circumstances demonstrated by the prescriber.

The prescriber regulatory agencies are also required to adopt rules for granting waivers that are consistent with the TSBP rules. On November 15, 2019, the TSBP held a work group meeting of the regulatory agencies. Participants offered suggestions to make broad sweeping waiver guidelines that had no basis in economic hardship or technological limitations. For example, one proposal was to exempt all areas with a population under 50,000. In Texas 184 of 254 counties have a population under 50,000, and 899 of 961 cities have a population less than

50,000. Many practitioners in suburban areas that do not lack technology or access to patients, such as Cinco Ranch outside of Houston or Coppell in the DFW area, would have automatically been waived from the EPCS provisions. These proposals were not adopted by the TSBP.

At the TSBPs February 2020 meeting, rules were proposed that reiterated the statute. Pharmacy groups raised concerns that the language did not “establish recommendations and standards for circumstances in which to grant a waiver”. (See the yellow highlights in the attached exhibit). At the August 2020 meeting an amended rule was proposed that adds some factors to be considered, such as special situational factors affecting cost, likely impact on profitability, and any available measures to mitigate the economic impact. (See the blue highlights in the attached exhibit). This rule will be up for adoption at the November 2020 TSBP Board meeting.

What is Electronic Prescribing. Electronic prescribing (E Prescribing) refers to the secure transmission of an electronically prepared prescription that is authorized and transmitted from the prescriber to the pharmacy. E-prescribing enables physicians and other medical practitioners to send prescriptions to the patient’s pharmacy of choice in an electronic format instead of handwriting, faxing or calling in prescriptions. A fax is not an electronic prescription. Of the 85,000+ prescribers 77.8% sent at least one electronic prescription to a pharmacy over their Electronic Health Record System in September.

What is different about Electronic Prescribing of a Controlled Substance (EPCS). E-prescribing of controlled substances is regulated by the Drug Enforcement Agency (DEA), which has allowed prescriptions for controlled substances to be issued and transmitted electronically since June 1, 2010. Under the federal rules, any software used by the prescriber or pharmacy must be able to import, display and store required contents for each prescription received. As a result, each party must either purchase certified software or hire a qualified third party to audit the application to assure compliance with DEA requirements. Texas has since adopted rules that align with the federal requirements for electronic prescribing, thereby allowing for prescriptions for controlled substances to be electronically consistent with federal standards. There are over 700 approved software providers for this application.

Of the 85,000+ prescribers in Texas (not including veterinarians or dentists in this count), 77.8% sent at least one electronic prescription to a pharmacy over their Electronic Health Record System in September 2020. Of the active e-prescribers, last month all but 1% (76.5% of prescribers) transmitted an electronic prescription on Electronic Health Record (EHR) software that is EPCS certified and audit approved. Some 40,570 or 47.6% of prescribers have enabled the EPCS feature by following the one time steps of enrolling (providing proof of identity), establishing a two-factor identification process to log into the system and setting access controls. More than 94 percent of pharmacies in Texas are EPCS enabled today.

Why require Electronic Prescribing of a Controlled Substance (EPCS). Data from self-reported drug abusers suggest that between 3% and 9% of diverted opioid prescriptions are tied to forged prescriptions. In 2018 there were 35,185,839 prescriptions filled for controlled substances: 11% of all prescriptions. The street value of opioids is so great that the Texas State Board of Pharmacy reports the black-market value of one Texas 50-sheet-prescription-pad with the new forgery and theft protection features is \$16,000. Reducing the number of paper prescriptions for controlled substances is one measure to curb fraud, waste, and abuse. Mandating EPCS assures the majority of prescribers comply.

Electronic prescribing of controlled substances adds new dimensions of safety and security to the prescribing process. Electronic controlled substance prescriptions cannot be altered, cannot be copied, and are electronically trackable. Furthermore, the federal DEA rules for electronic controlled substances prescriptions establish strict security measures, such as two-factor authentication, that reduce the likelihood of fraudulent prescribing. Notably, the state of New York saw a 70% reduction in the rate of lost or stolen prescription forms after implementing its own mandatory e-prescribing law. (The NY statistic was relayed by Anita Murray, Deputy Director, New York State Department of Health at the Harold Rogers Prescription Drug Monitoring Program National Meeting on September 6, 2017.) And continues to see reductions today.

Electronic prescribing practices improves patient care and outcomes. Electronic prescribing eliminates handwriting errors, and the technology allows prescribers to track whether the prescription was filled and how often it is refilled. Electronic prescribing tools also enable clinical decision-making at point of care; when electronic prescribing is part of a healthcare provider's electronic health record system, prescriptions can be checked for interactions with patient medications, health conditions, and allergies. This serves to improve patient outcomes.

Studies show that electronic prescriptions are less prone to errors. According to a study conducted at a Johns Hopkins Medication outpatient pharmacy, 89% of handwritten prescriptions failed to meet best practice guidelines or were missing information that would otherwise be prompted by an electronic prescribing system. By comparison, not a single prescription in that study issued electronically contained these types of errors.

A study shows that electronic prescribing practices reduce the number of prescriptions that go unfilled and serve to improve medication adherence. A 2012 study⁴ by Surescripts indicates that e-prescribing increases first fill medication adherence by 10% with the potential to save nationally \$140-\$240 billion over the next 10 years. The data revealed a 10% increase in new prescriptions that were picked up by the patient among physicians who adopted e-prescribing versus those physicians that did not. As many as 50% of patients do not adhere fully to their medication treatment. The study analyzed 40 million prescription records comparing e-prescriptions to paper, phoned- and faxed-prescriptions. E-prescribing technology allows healthcare providers to monitor and improve patient first fill adherence, as patients are more likely to fill prescriptions that are sent electronically to their pharmacy, as opposed to having to take the prescription to the pharmacy themselves.

The Law provides for Exemptions and Waivers. During the 86th Legislative Session, 2019, Rep. Zerwas (R-Houston) and Sen. Kolkhorst (R-Brenham), working with Texas Attorney General Ken Paxton, pushed to pass this legislation because of the aforementioned benefits. They started the bill by including exemptions requested by medical groups and from lessons learned in other states, like New York, who implemented a statewide mandate requiring ALL prescriptions be electronically prescribed. As a result, HB 2174 contains ten (10) exemptions and 3 (waivers). (*See Section 7, HB 2174, Sec. 481.0755, Occupations Code*)

Exemptions include:

1. Veterinarians,
2. Temporary technological or electronic failure,
3. Prescriptions to be dispensed out of state,
4. When the prescriber and dispenser are in the same location or same license, such as a hospital,
5. Prescriptions too long to fit in the allowed space, such as some compounded drugs,
6. Prescriptions that require additional information that does not fit in the EPCS allowable space,
7. Non patient specific prescriptions, such as a prescription to treat a diagnosed patient's partner for a sexually transmitted disease,
8. Drugs under a research protocol,
9. Prescribers that receive a waiver under this law; and
10. When an electronic prescription may delay the person getting the prescription filled, such as a late-night emergency room visit when the patient may not know which pharmacy is open that has the medication.

Prescribers may apply for a one-year waiver under the law. They must reapply each year for the waiver. Waivers can be granted by the regulatory board for the following three (3) reasons (*Sec. 481.0756, Occupations Code*):

1. Economic hardship,
2. Technological limitations not within control of the prescriber, or
3. Other exception circumstances demonstrated by the prescriber.

Some Prescribers Opposed EPCS during Session. The authors of the legislation heard concerns from some prescribers and addressed those concerns by providing exemptions and waivers (as listed above). Many of the concerns, however, have been disproved.

Opponents argued the cost to upgrade the office electronic medical records software can be costly. There is 700+ EHR software companies that provide DEA approved and audited electronic prescribing capabilities. An April 2018 report published by Point-of-Care Partners contains a chart listing the costs reported by the 15 most widely used EHR software providers. The report shows EPCS costs vary from “included in ongoing cost” up to \$250 per prescriber annually. The legislation provides for a waiver for economic hardship.

Opponents argued the Return on Investment (ROI) is negative if a prescriber writes a limited number of prescriptions for controlled substances. A 2012 White Paper by the American Dental Association noted that office efficiency would occur with EPCS as “over time, the ability to prescribe in a clear and unambiguous way, considering the member’s formulary and other medications, speeding processing of refill requests, and reducing callbacks will generate efficiency and reduce costs.” Additionally, as the health care system transitions to value-based reimbursement EPCS provides multiple benefits including inferred adherence by reporting fills and refills. The programs can also provide access to comprehensive patient medication history including allergies and drug interactions, and alerts are built into some systems.

Opponents argued the verification process is cumbersome and time consuming. Much like applying for a driver’s license, enrolling in EPCS does require verification of identity. To assure it is the DEA registrant being authorized, the prescriber must also complete two additional steps: set-up of the two-factor authentication and confirmation of identity by a third party. This process is a onetime process. If the prescriber’s software provider remains in DEA compliance, the steps would not need to be repeated.

Opponents argued EPCS creates additional barriers, such as:

- Unable to delegate the transmission of EPCS prescriptions to a staff member. EPCS does not change the current DEA restrictions on the prescribing of controlled substances.
- Patients at an emergency room may not have a preferred pharmacy on file. Prescribers consistently ask or confirm the patients preferred pharmacy. In an emergency room setting that would not change.
- A patient’s preferred pharmacy may close before the patient can get there to pick up medications. Having a paper prescription allows that person to go to the pharmacy with hours that fit their schedule. The law provides waivers for physicians to be able to write a paper prescription for situations that would delay a patient receiving their medication. That would include after-hour situations.

The Federal government passed mandatory EPCS for Medicare. In October of 2018, Congress passed, and President Trump signed into law H.R. 6, a comprehensive bill designed to address the opioid abuse epidemic. Included in the law was a mandate for electronic prescribing for controlled substances (EPCS) for prescription drugs covered under Medicare. The deadline to comply with this section of the new law is January 1, 2021. Due to the pandemic, CMS was delayed in seeking public comment for the rules to implement the law. At this time, the effective date has not been delayed.

During the legislative session opponents argued that the implementation date for Texas should be tied to the federal implementation date and delayed if the federal start date is delayed. Rep. Zerwas, Sen. Kolkhorst and AG Ken Paxton denied that request noting that there are sufficient exemption and waivers in the law to allow for a delay for the prescribers that have an economic hardship or lack technology, but the benefits of getting paper prescriptions for opioids off of the street sooner rather than later far out-weighs the arguments against implementation.

Conclusion. With a street value of \$16,000 per 50-page-prescription-pad used for controlled substances, implementing EPCS in Texas on time is imperative to reduce the number of paper prescriptions on the street that can be altered or forged, and to curb fraud, waste and abuse. It is unclear at this time how many waivers will be granted to prescribers by their regulating entities and on what ground those will be granted. We strongly encourage continued oversight of the measure as it is implemented beginning January 1, 2021. Broad waiver approval without respect to actual economic need or technological issues, will weaken this initiative aimed at keeping illegal and excess opioids off the streets and out of homes.

If you have any questions please do not hesitate to contact me at the number below or Janis Carter, TFDS consultant, at (512)914-3652 or jcarter@carterstrategies.com.

Yours Very Truly,

A handwritten signature in dark ink, appearing to read "Ken Breda". The signature is fluid and cursive, with the first name "Ken" and last name "Breda" clearly distinguishable.

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EXHIBIT - TITLE 22 EXAMINING BOARDS, PART 15 TEXAS STATE BOARD OF PHARMACY, CHAPTER 315
CONTROLLED SUBSTANCES §315.3 Prescriptions.

53 (c) Electronic ~~prescribing~~[prescription].

54 (1) A practitioner is permitted to issue and to dispense an electronic controlled substance
55 prescription only in accordance with the requirements of the Code of Federal Regulations, Title
56 21, Part 1311.

57 (2) Effective January 1, 2021, a prescription for a controlled substance is not required to
58 be issued electronically and may be issued in writing if the prescription is issued:

59 (A) in circumstances in which electronic prescribing is not available due to temporary
60 technological or electronic failure; or

61 (B) by a practitioner to be dispensed by a pharmacy located outside this state.

62 (3) A prescriber may apply for a waiver from the electronic prescribing requirement by:

63 (A) submitting a waiver request form to the agency that issued the license,
64 certification, or registration to the prescriber, including any information requested on the
65 form; and

66 (B) demonstrating circumstances necessitating a waiver from the requirement,
67 including:

68 (i) economic hardship, as determined by the agency that issued the license,
69 registration, or certification to the prescriber on a prescriber/by prescriber basis, taking
70 into account factors including:

71 (I) any special situational factors affecting either the cost of compliance or ability to
72 comply,

73 (II) the likely impact of compliance on profitability or viability, and

74 (III) the availability of measures that would mitigate the economic impact of
75 compliance;

76 (ii) technological limitations not reasonably within the control of the prescriber; or

77 (iii) other exceptional circumstances demonstrated by the prescriber.

78 (C) A waiver may be issued to a prescriber for a period of one year as specified in
79 Chapter 481 of the Texas Controlled Substances Act. A prescriber may reapply for a
80 subsequent waiver not earlier than the 30th day before the date the waiver expires if the
81 circumstances that necessitated the waiver continue.